

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
LISA A. HAILE
GRAY GARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE, SUITE 1100
SAN DIEGO, CA 92121-2133

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

24 MAY 2005

Applicant's or agent's file reference JHU2010WO	FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US04/22698	International filing date (day/month/year) 15 July 2004 (15.07.2004)	Priority date (day/month/year) 15 July 2003 (15.07.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 38/00 and US Cl.: 514/12		
Applicant THE JOHNS HOPKINS UNIVERSITY		

1. This opinion contains indications relating to the following items:

<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Box No. I Basis of the opinion
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Box No. II Priority
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Box No. IV Lack of unity of invention
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Box No. VI Certain documents cited
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Box No. VII Certain defects in the international application
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Box No. VIII Certain observations on the international application

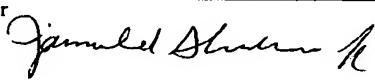
2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Sheela J. Huff  Telephone No. 571272-1600
--	--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/22698

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing
 table(s) related to the sequence listing

b. format of material

in written format
 in computer readable form

c. time of filing/furnishing

contained in international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.

3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/22698

Box No. II Priority

1. The following document has not yet been furnished:

copy of the earlier application whose priority has been claimed (Rules 43bis.1 and 66.7(a)).
 translation of the earlier application whose priority has been claimed (Rules 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. This opinion has been established as if no priority has been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

The priority claim is considered invalid because none of the claims are supported by the priority application.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/22698

Box No. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
 paid additional fees
 paid additional fees under protest
 not paid additional fees
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is:
 complied with
 not complied with for the following reasons:
See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
 all parts.
 the parts relating to claims Nos. 1-22 (peptides)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/22698

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-22 (peptides)</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>1-22 (peptides)</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-22 (peptides)</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-22 (peptides) meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed invention.

Claims 1-22 (peptides) meet the criteria set out in PCT Article 33(4), and thus the industrial applicability because the subject matter claimed can be made or used in industry.